Medtrade

Innovative Medical Products

MAY 10 2011

**SECTION 2:** **510(k) SUMMARY**

## 2.1 Sponsor

Medtrade Products Limited
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Registration Number: 9614493

Contact Person: Jonathan Ranfield
Quality & Regulatory Director

## 2.2 Date Summary was Prepared

February 3, 2011.

## 2.3 Device Information

Proprietary Name: CELOX Rapid Z-Fold Gauze

Common Name: CELOX Rapid

Classification Name: Dressing, Unclassified

## 5.4 Predicate Device

Medtrade Products Limited: CELOX Hemostatic Granules on Sheet (K080097)

## 5.5 Device Description

*Components* – CELOX Rapid is composed of chitosan

*Mechanism of Action* – CELOX Gauze achieves its principle intended action (hemostasis) by acting as a delivery system for the Celox Granules creating a physical barrier or seal to stop the flow of blood. When in contact with a wound and upon contact with blood or exudate, in combination with manual pressure to the wound, the CELOX Granules heat bonded on to the CELOX Rapid quickly form a strong seal that completely covers the wound.

### 5.6 Intended Use

**CELOX Rapid Gauze (Rx)** is indicated for temporary external use to control moderate to severe bleeding.

**CELOX Rapid Gauze (OTC)** is indicated for temporary external use to control bleeding of lacerations, minor cuts, and abrasions.

### 5.7 Substantial Equivalence

CELOX Rapid Gauze is identical in manufacturing route, packaging and irradiation as CELOX Hemostatic Granules on Sheet K080097 cleared on July 9, 2008.

CELOX Rapid Gauze has substantially equivalent indications to CELOX Hemostatic Granules on Sheet K080097 in that they are indicated for temporary external use to control moderate to severe bleeding (Rx) and temporary external use to control bleeding of lacerations, minor cuts, and abrasions (OTC).

CELOX Rapid Gauze uses the same safe and effective technology as CELOX Hemostatic Granules on Sheet K080097. The subject device and predicate devices are made from materials which have demonstrated satisfactory biocompatibility, are sterile, single use devices.

### 5.7 Performance Testing

Biocompatibility Testing:

Biocompatibility has been reviewed in accordance with ISO10993 and FDA Blue Book memo G95-1.

To support:

To Control Moderate To Severe Bleeding, Works in Hypothermic Conditions, No Heat Generated in Use, Reduces Blood Loss, previously provided and cleared under (K080097).

In Vitro Testing to support:

- Rapid Packing
- High Volume Gauze Strip
- Promotes Rapid Wound Adhesion

Animal Studies

Animal Study 1 – The efficacy of Celox Rapid Gauze in a femoral artery wound model. To support

- Stops bleeding fast
- Rapidly controls bleeding

Clinical Study – Not Applicable.

### 5.8 Conclusion

CELOX Rapid Gauze induces hemostasis by the absorption of water in the blood to form a robust gel plug the same as CELOX Hemostatic Granules on Sheet (K080097) predicate device.

CELOX Rapid Gauze has been shown in testing to provide rapid haemorrhage control in a swine model of lethal arterial extremity.

Medtrade Products believes that, as a result of the biocompatibility testing in vitro testing, and non-clinical animal testing, CELOX Rapid Gauze is safe and effective as an aid in the control of temporary external bleeding associated with moderate to severe bleeding and the control of minor external bleeding of laceration, minor cuts and abrasions.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Medtrade Products Limited
% Mr. Jonathan Ranfield
Quality and Regulatory Director
Electra House, Crewe Business Park
Crewe, Cheshire CW1 6GL
United Kingdom

MAY 10 2011

Re: K110386
Trade/Device Name: CELOX Rapid Gauze
Product Code: FRO
Dated: February 3, 2011
Received: February 10, 2011

Dear Mr. Ranfield:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

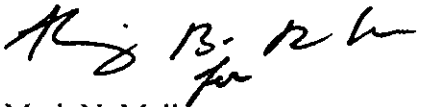
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

# Indications for Use

510(k) Number (if known): K110386

Device Name: CELOX Rapid Gauze

Indications For Prescription Use:

CELOX Rapid Gauze is indicated for temporary external use to control moderate to severe bleeding.

Prescription Use __X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K110386

# Indications for Use

510(k) Number (if known): K110386

Device Name: CELOX Rapid Gauze

Indications For OTC (Over The Counter) Use:

CELOX Rapid Gauze is indicated for temporary external use to control bleeding of lacerations, minor cuts, and abrasions.

Prescription Use _____ AND/OR Over-The-Counter Use ___X____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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Division of Surgical, Orthopedic,
and Restorative Devices



510(k) Number K110386